

## **PCT**

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's o	r ager	nt's file reference		See N	Notification of Transmittal of International
PU3375/PCT			FOR FURTHER AC	TION Prelim	ninary Examination Report (Form PCT/IPEA/416)
International application No.			International filing date (da	ay/month/year)	Priority date (day/month/year)
PCT/EP9	3/062	278	05/10/1998		07/10/1997
Internationa A61K31/0		nt Classification (IPC) or	national classification and IPC		
Applicant GLAXO	ROL	JP LIMITED et al.			
1. This in and is	trans	tional preliminary exa mitted to the applican	mination report has been p t according to Article 36.	prepared by this	s International Preliminary Examining Authority
2. This F	REPO	RT consists of a total	of 5 sheets, including this	cover sheet.	
b	en a	mended and are the b	ied by ANNEXES, i.e. she asis for this report and/or 607 of the Administrative	sheets containi	ription, claims and/or drawings which have ng rectifications made before this Authority der the PCT).
These	ann	exes consist of a total	of sheets.		
3. This r	eport	contains indications r	elating to the following item	ns:	
- 1	$\boxtimes$	Basis of the report			
П		Priority			
Ш	$\boxtimes$	Non-establishment of	of opinion with regard to no	velty, inventive	step and industrial applicability
IV	$\boxtimes$	Lack of unity of inve			
V	<ul> <li>Neasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement</li> </ul>				
VI		Certain documents	cited		
VII		Certain defects in th	e international application		•
VIII		Certain observations	s on the international applic	ation	
			,-		
Date of su	omissi	on of the demand		Date of comple	tion of this report
05/05/1999					2 <b>8. 02. 🕰</b>
		g address of the internat sining authority:	ional .	Authorized office	Cer grande manue
preliminary		opean Patent Office		7	
D-80298 Munich				Cattell, Jam	es 📜 💇 🏸
Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465			зоро ерти а	Telephone No.	+49 89 2399 8468

International application No. PCT/EP98/06278

in

### I. Basis of the report

1.	This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):					
	Des	cription, pages:				
	1-15	i	as originally filed			
	Clai	ms, No.:				
	1-10	)	as originally filed			
2.	The	ámendments hav	e resulted in the cancellation of:			
		the description,	pages:			
		the claims,	Nos.:			
		the drawings,	sheets:			
3.		This report has b considered to go	een established as if (some of) the amendments had not been made, since they have be beyond the disclosure as filed (Rule 70.2(c)):			
4.	Add	litional observatio	s, if necessary:			
ш	. No	n-establishment	of opinion with regard to novelty, inventive step and industrial applicability			
Ti	ne qu to b	estions whether the industrially appli	e claimed invention appears to be novel, to involve an inventive step (to be non-obvious cable have not been examined in respect of:			
		the entire interna	tional application.			
	Ø	claims Nos. 4, 8	(1, 5, 9 partially), 5-7(IA) .			
b	ecau	se:				
		the said internat	onal application, or the said claims Nos. relate to the following subject matter which does emational preliminary examination ( <i>specify</i> ):			

International application No. PCT/EP98/06278

		the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
		the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinior could be formed.
	⊠	no international search report has been established for the said claims Nos. 1, 4, 5, 8, $9.\ .$
IV.	Lac	k of unity of invention
1.	In r	esponse to the invitation to restrict or pay additional fees the applicant has:
		restricted the claims.
		paid additional fees.
		paid additional fees under protest.
		neither restricted nor paid additional fees.
2.	⊠	This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3.	Thi	s Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 i
		complied with.
	⊠	not complied with for the following reasons:
		see separate sheet
4.		nsequently, the following parts of the international application were the subject of international preliminary mination in establishing this report:
		all parts.
	×	the parts relating to claims Nos. 2, 3, 6-7, 10 (1, 5, 9 partially)

International application No. PCT/EP98/06278

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial
applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims 1, 2, 3,5, 6, 7 No: Claims 9.19

Inventive step (IS)

Yes: Claims

No: Claim

Industrial applicability (IA)

Claims 1, 2, 3, 5,6, 7

Yes: Claims 1, 2, 3, 9, 10 No: Claims

2. Citations and explanations

see separate sheet

## INTERNATIONAL PRELIMINARY International application No. PCT/EP98/06278 EXAMINATION REPORT - SEPARATE SHEET

III.

- An international examination report can only be drawn up on searched subjectmatter (Rule 66.1(e) PCT).
- Claims 5, 6 and 7 relate to subject-matter considered by this Authority to be
  covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be
  formulated with respect to the industrial applicability of the subject-matter of these
  claims (Article 34(4)(a)(i) PCT).

IV.

The IPEA agree with the assessment of unity made by the ISA under Rule 13.1 PCT. Once it is known and obvious that and 5-HT<sub>3</sub> receptor antagonists can be used to treat IBS (see section V below) the use of the individual agents exemplified in claim 8 are regarded as being different "inventions".

٧.

- Document D1 (EP-A-0,306,323) discloses on page 4 lines 1 and 26 the use of alosetron to treat IBS.
  - Document D2 (Foster et al 1997) and D3 (Barman et al 1996) disclose the use of alosetron to treat IBS.
  - These disclosures fall within the scope of product claims 9 and 10 under Article 33(2) PCT.
- Once the use of alosetron in IBS patients is known (from an one of D1 to D3) the
  optimisation of the treatment would be obvious. The discovery of treating female
  nonconstipated IBS patients would occur inevitable from these obvious trials.
   Claims 1, 2, 3, 5, 6 and 7 therefore do not meet the requirements of Article 33(3)
  PCT

16

# CATENT COOPERATION TRETY

PCT

ESSO 1 / DIAR 2000

See Notification of Transmittal of International

Preliminary Examination Report (Form PCT/IPEA/416)

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

FOR FURTHER ACTION

Applicant's or agent's file reference

PU3375/PCT

International application No.			International filing date (d	day/month/year)	Priority date (day/month/y	ear)		
PCT/EP98/06278 05/10/1998					07/10/1997			
	International Patent Classification (IPC) or national classification and IPC A61K31/00							
Applicant								
1	aro	UP LIMITED et al.						
				11				
		ational preliminary exami smitted to the applicant a		prepared by this inte	ernational Preliminary Exa	amining Authority		
2. This F	REPO	PRT consists of a total of	5 sheets, including this	cover sheet.				
ь	en a	mended and are the bas	sis for this report and/or	sheets containing re	n, claims and/or drawing: ctifications made before			
		ule 70.16 and Section 60				ŕ		
These	ann	exes consist of a total of	sheets.					
3. This r	onor	contains indications rela	iting to the following iter	ns:				
J. Inist	ehou	, contains mulcations fela	ming to the following itel					
1		Basis of the report						
- 11		Priority						
III				verty, inventive step	and industrial applicabilit	ту		
IV.		Lack of unity of invention		naard to povotty inv	antivo eton or industrial a	nnlicability:		
V ☐ Reasoned statement under Article 35(2) with re- citations and explanations suporting such states				annive step or industrial a	ррпсавшку,			
VI		Certain documents cite	ed					
VII		Certain defects in the in	nternational application					
VIII		Certain observations of	n the international appli	cation				
						-/-		
Date of sub	missi	on of the demand		Date of completion of	this report			
05.05/:5					2 8.02.00			
05/05/1999				7 0.02				
	Name and mailing address of the international preliminary examining authority:			Authorized officer		STATES MUNICIPAL		
preliminary		nining authority: opean Patent Office				( <u>( ( ( )</u>		
<i>(</i> )	D-8	0298 Munich	٠	Cattell, James				
<del>- 9</del>		+49 89 2399 - 0 Tx: 52365 : +49 89 2399 - 4465	o epmu a	Telephone No. +49 8	9 2399 8468	SON DIE THE T		
Form PCT/IF	EA/4	09 (cover sheet) (January 19	994)					



International application No. PCT/EP98/06278

1	Ras	iis.	of	the	repor	t

<ol> <li>This report has been drawn on the basis of (substitute sheets which have been furnished to the n response to an invitation under Article 14 are referred to in this report as "originally filed" and are the report since they do not contain amendments.):</li> </ol>					been furnished to the receiving Offic originally filed" and are not annexed	:e to
	Des	cription, pages:				
	1-15	5	as originally filed			
	Clai	ms, No.:				
	1-10	)	as originally filed			
2.	The	amendments have	resulted in the cancella	ation of:		
		the description,	pages:			
		the claims,	Nos.:			
		the drawings,	sheets:			
3.		This report has be considered to go b	en established as if (so beyond the disclosure a	ome of) the amendments had as filed (Rule 70.2(c)):	d not been made, since they have be	er
4.	Add	litional observation	s, if necessary:			
				to novelty, inventive step a		
TI or	to be	estions whether the industrially applic	e claimed invention app able have not been exa	pears to be novel, to involve amined in respect of:	an inventive step (to be non-obvious	i),
		the entire internat	ional application.			
	×	claims Nos. 4, 8 (	1, 5, 9 partially), 5-7(IA)			
be	ecaus	se:				
		the said internation not require an inter	onal application, or the s emational preliminary e	said claims Nos. relate to the xamination ( <i>specify</i> ):	e following subject matter which does	5

International application No. PCT/EP98/06278

		the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):
		the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
	×	no international search report has been established for the said claims Nos. 1, 4, 5, 8, 9
IV.	Lac	ck of unity of invention
1.	In r	esponse to the invitation to restrict or pay additional fees the applicant has:
	П	restricted the claims.
		paid additional fees.
		paid additional fees under protest.
		neither restricted nor paid additional fees.
2.	⊠	This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3.	Thi	s Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 i
		complied with.
	×	not complied with for the following reasons:
		see separate sheet
4.		nsequently, the following parts of the international application were the subject of international preliminary amination in establishing this report:
		all parts.
	×	the parts relating to claims Nos. 2, 3, 6-7, 10 (1, 5, 9 partially)





International application No. PCT/EP98/06278

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Yes: Novelty (N)

Claims 1, 2, 3,5, 6, 7 Claims 9.19 No:

Inventive step (IS)

Yes: Claims

No:

Claims 1, 2, 3, 5,6, 7

Yes: Industrial applicability (IA) No:

Claims 1, 2, 3, 9, 10 Claims

2. Citations and explanations

see separate sheet

## International application No. PCT/EP98/06278

# INTERNATIONAL PRELIMINARY Inte

III.

- An international examination report can only be drawn up on searched subjectmatter (Rule 66.1(e) PCT).
- Claims 5, 6 and 7 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

IV.

The IPEA agree with the assessment of unity made by the ISA under Rule 13.1 PCT. Once it is known and obvious that and 5-HT<sub>3</sub> receptor antagonists can be used to treat IBS (see section V below) the use of the individual agents exemplified in claim 8 are regarded as being different "inventions".

٧.

- Document D1 (EP-A-0,306,323) discloses on page 4 lines 1 and 26 the use of alosetron to treat IBS.
  - Document D2 (Foster et al 1997) and D3 (Barman et al 1996) disclose the use of alosetron to treat IBS.
  - These disclosures fall within the scope of product claims 9 and 10 under Article 33(2) PCT.
- Once the use of alosetron in IBS patients is known (from an one of D1 to D3) the
  optimisation of the treatment would be obvious. The discovery of treating female
  nonconstipated IBS patients would occur inevitable from these obvious trials.
  Claims 1, 2, 3, 5, 6 and 7 therefore do not meet the requirements of Article 33(3)
  PCT.